LETTERS TO THE EDITOR

Influence of perfusion technique and pH management strategy during coronary artery bypass surgery

To the Editor:

In a "double-blind," randomized study of 316 patients, which compared two methods of perfusion techniques (nonpulsatile vs pulsatile) and pH management (alpha-stat versus pH-stat), Murkin and colleagues[1] report that pulsatile perfusion resulted in a highly significant reduction in myocardial infarction, death, the need for an intraaortic balloon pump, and major complications. These dramatic conclusions are significantly flawed, however, both by fundamental limitations in the study design and by the particularly high mortality and morbidity in the nonpulsatile group:

The operations were performed by four surgeons, two of whom used crystalloid cardioplegia and two of whom used blood cardioplegia (we are not told of the route of administration of the latter). The fact that the four surgeons performed 94, 99, 21, and 102 operations introduces a further major difference between the groups, because simple calculation reveals that between 36% and 39% of patients must have received one type of cardioplegia and 64% to 61% of patients the other. To complicate matters even further, the surgeons using crystalloid cardioplegia performed significantly more grafts with significantly shorter crossclamp times (by approximately 20 minutes) than those using blood cardioplegia. Despite the highly significant differences in cardioplegic techniques, number of grafts, and duration of ischemia in the two groups, which are all major independent determinants of cardiac morbidity, the authors merely state, without providing any objective data, that "cardioplegia type did not correlate with adverse outcome."

The use of the term "double-blind" in the abstract is totally misleading. The four operating surgeons must have been aware both of the mode of perfusion (by observation of analog displays of arterial pulse pressure) and the type of cardioplegic solution administered. If so, it is conceivable that individual surgeons were influenced, albeit subconsciously, in the number of grafts they performed (as indeed was the case for surgeons using crystalloid cardioplegia) or the need for an intraaortic balloon pump. The fact that the research nurse and technician were blinded to the mode of perfusion is irrelevant with regard to the collection of objective data such as the number of patients who died, who had electrocardiographically confirmed infarcts, or who required intraaortic balloon pumps.

A further major concern in this study is the particularly high mortality and morbidity in the nonpulsatile group considering their favorable demographic features (their mean age was 61 years, and 95% had a left ventricular ejection fraction >35%). A mortality of 6% and a requirement for an intraaortic balloon pump in 7% of such good-risk elective patients appears particularly excessive and is unlikely to be simply explained by the use of nonpulsatile perfusion.

Although the authors are to be congratulated on undertaking a potentially important clinical trial, major reservations regarding their conclusions must remain until objective data are presented to eliminate the effects of different surgeons, cardioplegic techniques, number of grafts, and ischemic times on postoperative cardiac mortality and morbidity. Furthermore, the possibility that the apparent benefit of pulsatile perfusion was simply due to an excessively high mortality in the nonpulsatile group for some other reason must remain a genuine concern.

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REFERENCE

1. Murkin JM, Martzke JS, Buchan AM, Bentley C, Wong CJ. A randomized study of the influence of perfusion technique and pH management strategy in 316 patients undergoing coronary artery bypass surgery. I. Mortality and cardiovascular morbidity. J THORAC CARDIOVASC SURG 1995;110:340-8.

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Reply to the Editor:

On behalf of my coauthors I would like to thank Dr. Taggart for his insightful analysis of our paper "A Randomized Study of the Influence of Perfusion Technique and pH Management Strategy in 316 Patients Undergoing Coronary Bypass Surgery. I. Mortality and Cardiovascular Morbidity." He has identified a number of contentious issues regarding the study design, and he raises concern regarding overall morbidity and mortality rates in the nonpulsatile group.

With regard to study design, we agree with Dr. Taggart that the very real differences in composition of cardioplegic solutions, route of administration (one surgeon used blood cardioplegia administered retrogradely, $n = 21$; the other three administered the cardioplegic solution anterogradely), number of grafts, and duration of crossclamp between cardioplegia types (blood versus crystalloid), *if controlled for,* might be expected to result in differences in outcome across cardioplegia groups. It is precisely because of these many uncontrolled variables, however, that cardioplegic type was not significant in outcome (page 343: death, myocardial infarction, arrhythmia, and insertion of an intraaortic balloon pump vs cardioplegia type, univariate analysis, $p = 0.11$). More grafts and shorter crossclamp times were associated with use of crystalloid cardioplegia. Usage of blood cardioplegia was associated with the converse, but presumably enabled a longer